

*Breathing in Harmony: An Assessment of Unique Inspiratory Muscle Training Techniques  
Utilized by Patients with COPD in Pulmonary Rehabilitation*

**An Honors Thesis (HONR 499)**

**by**

*Allyson Garrett*

**Thesis Advisor**

*Nicole Kaontz*

**Signed**

**Ball State University  
Muncie, Indiana**

*May 2016*

**Expected Date of Graduation**

*May 2016*

SpColl  
Undergrad  
Thesis  
LD  
2489  
24  
2016  
G377

# **Abstract**

The current research study was designed to assess the potential of utilizing harmonica playing as a form of inspiratory muscle training (IMT), and its effects on breathing efficiency and perceived dyspnea, as well as the quality of life of patients with Chronic Obstructive Pulmonary Disease (COPD) currently enrolled in a comprehensive Cardiopulmonary Rehabilitation program. This was accomplished through the comparison of two types of inspiratory muscle training techniques: incentive spirometry via a Voldyne and harmonica playing.

### **Acknowledgements**

I would like to thank Nicole Koontz for advising me through this project. Her guidance and encouragement during this long and challenging task were just a small fraction of the help I received from her during my four years at Ball State University.

I would like to thank Heather Cochran for all of her assistance, advice, and effort in ensuring that this project went smoothly. Without her, this final product would not have been successful.

I would also like to acknowledge Katrina Riggin for her support, her ideas and suggestions, and her help with getting my project up and running with the Institutional Review Board (IRB).

Additionally, I would like to express my gratitude to Alfreda Bright with the IRB and her assuring that I took all of the necessary steps to get my project proposal approved.

Lastly, I would like to thank my family and peers for inspiring me to persevere through this intimidating task.

## Table of Contents

|   |              |
|---|--------------|
| <b>Abstract.....</b>  | <b>1</b>     |
| <b>Introduction</b>   |              |
| What is COPD?.....  | 2            |
| The Role of Pulmonary Rehabilitation Programs in COPD.....          | 3            |
| The Potential of IMT in PR Programs.....                            | 4            |
| Utilization of Harmonica Playing as a Form of IMT.....              | 5            |
| The Current Research's Intent.....                                  | 6            |
| <b>Methods</b>  |              |
| Procedure.....  | 7            |
| Operationally Defining the Variables.....                           | 9            |
| Participants.....   | 10           |
| Materials.....  | 12           |
| <b>Results</b>  |              |
| Descriptive Statistics.....   | 13           |
| Inferential Statistics.....   | 15           |
| <b>Discussion</b>   |              |
| The Statistical Data.....   | 17           |
| Paired Samples t-Test for the Entire Sample.....                    | 18           |
| Paired Samples t-Test for Individual Groups' Pre-Post Measures..... | 19           |
| The Independent Samples t-Test Evaluating Change Scores.....        | 19           |
| Obstacles for the Current Research.....                             | 20           |
| The Feasibility of IMT as an Adjunct Therapy.....                   | 22           |
| The Rationale for Utilizing Harmonica Playing as a Type of IMT..... | 25           |
| Considerations for Future Research.....                             | 29           |
| The Current Research's Conclusions.....                             | 30           |
| <b>References.....</b>  | <b>33</b>    |
| <b>APPENDIX A: Institutional Review Board (IRB) Documents.....</b>  | <b>i</b>     |
| <b>APPENDIX B: Informed Consents.....</b>                           | <b>xi</b>    |
| <b>APPENDIX C: Data Collection Sheets.....</b>                      | <b>xviii</b> |
| <b>APPENDIX D: COPD Assessment Test (CAT).....</b>                  | <b>xxiv</b>  |
| <b>APPENDIX E: mMRC Breathlessness Scale.....</b>                   | <b>xxvi</b>  |



## Abstract

**THESIS:** Breathing in Harmony: An Assessment of Unique Inspiratory Muscle Training Techniques Utilized by Patients with COPD

**STUDENT:** Allyson Garrett

**DEGREE:** Bachelor of Science

**COLLEGE:** Applied Science and Technology

**SCHOOL:** School of Kinesiology

**DATE:** May 2016

**Purpose:** The current research study was designed to assess the potential of utilizing harmonica playing as a form of inspiratory muscle training (IMT), and its effects on breathing efficiency and perceived dyspnea, as well as the quality of life of patients with Chronic Obstructive Pulmonary Disease (COPD) currently enrolled in a comprehensive Cardiopulmonary Rehabilitation program. This was accomplished through the comparison of two types of inspiratory muscle training techniques: incentive spirometry via a Voldyne and harmonica playing. **Methods:** Pre- and post-data was collected from seven individuals with COPD currently enrolled in Cardiopulmonary Rehabilitation at IU Health Ball Memorial Hospital aged  $66.5714 \pm 8.82906$  (range 56-79, 4 males & 3 females). Analysis consisted of two groups, Group A and Group B. The commitment of the study participants included six weeks of their assigned IMT, in addition to their individualized exercise program that they were already participating in. Group A, the harmonica group, consisted of three individuals, and Group B, the Voldyne group, consisted of four. Pre- and post-study surveys were issued to assess the progress that each individual made throughout the six weeks of training. A document known as the Modified Medical Research Council Dyspnea Scale (mMRC) was used to evaluate each participant's breathlessness, and a quality of life survey, known as the COPD Assessment Test (CAT), was also issued before and after the 6-week training period. Statistical tests, including paired samples t-tests and an independent samples t-test were conducted to evaluate the significance of the collected data. **Results:** Significant differences were found ( $p\text{-value} < 0.05$ ) between the pre-post measures on the CAT for the entire sample and the pre-post measures on the CAT for Group A after the 6-week training period, indicating significant improvements in quality of life after 6 weeks of training in these particular tests. The independent samples t-test used to evaluate the change scores for the pre-post measures for each group revealed that Group A, the harmonica group, had change scores that were significantly larger than Group B, the Voldyne group. **Conclusion:** Harmonica training, as a form of inspiratory muscle training, can significantly improve the quality of life in patients with moderate to severe COPD, and, although not quite significantly, can also improve shortness of breath. Harmonica training also improved quality of life and perceived dyspnea significantly more than the Voldyne was able to accomplish. The results do not show a clear improvement or regression in terms of COPD symptoms, other than the enhanced quality of life of those participants who played the harmonica. Conducting a similar study with a larger sample size and measures of inspiratory muscle strength, forced expiratory volume in one second, and forced vitality capacity, may produce more concrete results and provide stronger evidence in support of the inclusion of harmonica training in a PR program.



## Introduction

### What is COPD?

Chronic obstructive pulmonary disease, more commonly referred to as COPD, is a preventable and treatable condition, and is relatively easy to diagnose. COPD is the fourth leading cause of death in the US, and it is estimated that COPD will become the third leading cause of death in America, and worldwide, by the year 2020 (Rennard and Stoner, 2005). COPD is characterized by airflow limitation that is not completely reversible. The nature of the airflow limitation is progressive and the lungs are sensitive to noxious particles or gases – primarily caused by cigarette smoking – as they initiate an abnormal inflammatory response in the pulmonary tissues (Celli, et al., 2004). The contribution that smoking makes to the pathogenesis of COPD is likely the cause of complacency towards the disease. COPD is a clear public health problem, but has attracted limited interest from the public or the research communities when compared to other major public health problems, as it is believed to be largely a self-inflicted illness (Rennard and Stoner, 2005).

Any patient with symptoms of cough, sputum production, or shortness of breath, otherwise known as dyspnea, or previous exposure to risk factors for the disease, should be considered for COPD diagnosis (Celli, et al., 2004). COPD has a mid-life onset with a slow progression of symptoms. Patients with COPD are victims of respiratory muscle dysfunction that possibly contributes to the detrimental effects of the disease, such as decreased quality of life, increased dyspnea, activity restrictions, and decreased exercise capacity (Alexander and Wagner, 2012). COPD is characterized by impaired lung function, hyperinflation, dead space ventilation, in addition to increased energy consumption that results in a reduced ventilatory capacity. These changes in pulmonary anatomy and physiology are associated with shortness of breath and

limitation of daily activities (Basoglu et al., 2004). Patients with COPD experience pathological changes in four different lung compartments, which include the central airways, peripheral airways, lung parenchyma, and vasculature of the lungs; these pathological changes vary in their presence amongst those with the disease (Celli, et al., 2004). Individuals with COPD often experience what are known as exacerbations, which are small-scale, transient worsening of respiratory symptoms and may cause specific signs and symptoms, such as increased dyspnea, productive cough with altered sputum, and fever. On the other hand, the symptoms could be more nonspecific, including malaise, fatigue, insomnia or sleepiness, and depression. Exacerbations are commonly associated with significant increases in health-care attention, hospitalization, and even death (Rodriguez-Roisin, 2000).

### **The Role of Pulmonary Rehabilitation Programs in COPD**

Patients with COPD are often referred to a Pulmonary Rehabilitation (PR) program as a mode of treatment, which encompasses a variety of services, including self-management education, retraining of breathing, psychosocial support, and exercise (Alexander and Wagner, 2012). Since the beginning of implemented control trials on PR in the mid-1970s, Pulmonary Rehabilitation has demonstrated clinically significant improvements in quality of life, dyspnea – or shortness of breath – during daily activities, and exercise capacity (Magadle, et al., 2007). In patients with COPD, exercise capacity, health-related quality of life, and activities of daily living are often impaired more drastically than lung function is impaired, and comprehensive Pulmonary Rehabilitation programs are designed to tackle the systematic consequences that accompany COPD (Magadle, et al., 2007).



The component of PR programs that seems to be most effective is the peripheral – preferably lower limbs – muscle exercise training, whereas the role of inspiratory muscle training (IMT), an intervention that has been incorporated into rehabilitation programs as an adjunct to general exercise of patients with COPD, continues to be controversial (Ambrosino, 2011). The data for such an intervention remain inconclusive, but IMT could be considered as an adjunctive therapy in PR programs, especially in those patients who are suspected or proven to have respiratory muscle weakness (Ambrosino, 2011), as it may serve to increase the strength of inspiratory muscles, improve breathing technique, and enhance the quality of life in those who experience chronic airflow limitation. IMT with inspiratory loading and its intention to improve strength and endurance of the muscles of inspiration, attempt to enhance respiratory muscle function in those who suffer from COPD (Larson, et al., 1988). The technique has earned significant attention for its capabilities in reversing muscle dysfunction that is experienced by COPD patients and the positive impact it has on exercise capacity, difficulty breathing and, thus, the overall quality of life.

### **The Potential of IMT in PR Programs**

An optimal inspiratory muscle training protocol for patients with COPD has not yet been defined. Analyzing the efficacy of IMT is difficult given the wide variety of patient characteristics, including the degree of hyperinflation, severity of airway obstruction, and respiratory muscle weakness (Lötters et al., 2002). All of these characteristics of COPD could influence the results and outcomes in various patients. In a meta-analysis conducted in 2002 that reviewed fifty-seven studies that investigated the efficacy of inspiratory muscle training in patients with COPD, it was discovered that inspiratory muscle training alone did in fact

significantly improve inspiratory muscle strength and endurance, and significantly decreased the sensation of dyspnea in COPD patients (Lötters et al., 2002), and increased functional exercise capacity. It was also observed that the extent of inspiratory muscle weakness did appear to play an important role in the efficacy of IMT as an adjunct to general exercise reconditioning (Lötters et al., 2002), indicating that weakness of inspiratory muscles could be an important prognostic factor of the efficacy of IMT. In order to have the greatest benefit, IMT should be incorporated into Pulmonary Rehabilitation programs directed at COPD patients with inspiratory muscle weakness.

### **Utilization of Harmonica Playing as a Form of IMT**

Inspiratory muscle training is typically performed using a pressure or resistance device for fifteen to thirty minutes on five to seven days a week (Alexander and Wagner, 2012). It has been noted that playing the harmonica may mimic IMT, based on the notion that the small holes in the harmonica provide a similarity in performing inspiration and expiration through a device that provides resistance and, thus, may provide similar benefits. In a study conducted by Alexander (2012), however, it was shown that harmonica playing did not prove to be any more beneficial, when combined with a traditional PR program, than the traditional PR program alone. Despite loose claims suggesting that harmonica playing is a therapy as similarly effective for improving breathing as IMT, in this study, harmonica playing did not result in improvements in inspiratory muscle strength and functional capacity as has been demonstrated with combined IMT and exercise training (Alexander and Wagner, 2012).

If harmonica playing supposedly does not effectively improve functional capacity during physical activity, the question is why are programs working to implement it? Studies have shown



that patient perception of shortness of breath decreases significantly after training with the harmonica, and their health-related quality of life shows improvement as well (Alexander and Wagner, 2012). Harmonica playing is an effective mode of delivery because it's enjoyable and affordable and can help patients improve their breathing dynamics (Alexander and Wagner, 2012).

### **The Current Research's Intent**

The intent of the current research study is to assess the effectiveness of harmonica playing, as a form of IMT, from a subjective standpoint, on breathing efficiency and perceived dyspnea, as well as quality of life and the ability to perform activities of daily living, in patients with COPD who are currently enrolled in Pulmonary Rehabilitation at IU Health Ball Memorial Hospital. The purpose of this study is to compare two types of inspiratory muscle training techniques in patients with COPD of various stages. The primary objective of this research is to determine if one form is more effective than the other, or if they are relatively equal in their potential to produce beneficial results in patients with COPD and their related inspiratory muscle weakness, or if either form is even beneficial at all.

The two techniques being assessed are incentive spirometry through the use of a Voldyne, and the playing of the harmonica. An incentive spirometer is a simple mechanical device that facilitates deep breathing, and the associated maximal lung inflation is believed to open collapsed alveoli in an effort to prevent and resolve atelectasis (Basoglu et al., 2004). As a result, the incentive spirometer and its benefits are recommended for COPD patients following an operation; however, its effectiveness in COPD patients, independent of surgery, is unknown. Incentive spirometry is designed to mimic natural sighing or yawning by encouraging the patient

to take long, slow, deep breaths, and can be utilized for inspiratory muscle training (Heydari, Farzad, and Ahmadi, 2013).

Most PR programs do not currently utilize IMT in their programs (Magadle, et al., 2007). Research has shown controversial results from the use of harmonica playing in terms of its ability to improve functional capacity, and the objective of this study is to see, over a short period of time, if harmonica training, which is Standard of Care for Phase II Cardiopulmonary Rehabilitation patients at Indiana University Health Ball Memorial Hospital, has any implications on individuals with COPD and their symptoms. Standard of Care, according to Medicine.net, is defined as “a diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance.” It is hypothesized that harmonica playing can be used as a way to provide inspiratory muscle training and has the potential to be just as effective as IMT through the use of an incentive spirometer, and that patients with COPD will benefit from harmonica training, as it will help improve shortness of breath and perception of effort when completing activities of daily living (ADLs), as well as enhancing the quality of life.

## **Methods**

### **Procedure**

Patients with moderate to severe COPD from the Cardiopulmonary Rehabilitation clinic of IU Health Ball Memorial Hospital were introduced to the research study via flyers created by the primary investigator. The purpose, expectations of the participants, risks, and potential benefits of the study, were laid out in an informed consent that was issued and explained to each participant, and signed by each participant to provide written consent, before they were permitted



to take part in the study. This important documentation was created in order to ensure that each subject was aware of the objectives of the study and was provided with a statement of confidentiality, as well as permission to withdraw from the study at any time if he or she may choose to do so. A Health and Insurance Portability and Accountability Act (HIPAA) authorization was also included in the informed consent.

Patients with COPD, in both Phase II and Phase III Cardiopulmonary Rehabilitation, were provided with the opportunity to be a subject of this research study. Patients were assigned to either Group A or Group B, and their assignments were dependent on the stage of Cardiopulmonary Rehabilitation they were currently enrolled in. Phase II of Cardiopulmonary Rehabilitation is the first stage of outpatient cardiac rehabilitation following discharge from the hospital. During this phase, patients are provided with an individualized exercise program and educational information to assist with lifestyle modifications. Educational classes include topics like smoking cessation, medicine review, coping, depression, nutrition and other topics of interest, and are taught by multidisciplinary teams, which include exercise physiologists, registered pharmacists, registered dietitians, stress counselors, nicotine counselors, diabetes educators, and other healthcare professionals (<http://iuhealth.org/ball-memorial/heart-vascular-care/>). Phase III of Cardiopulmonary Rehabilitation at IU Health Ball Memorial Hospital follows successful completion of Phase Two, or can begin with an order from the patient's physician. (<http://iuhealth.org/ball-memorial/heart-vascular-care/>).

After the opportunity to take part in the study was brought to the attention of all those individuals who qualified for participation, the primary investigator and the primary Cardiopulmonary Rehab Specialist at IU Health Ball Memorial Hospital recruited subjects for the research study. The sample collected was largely a convenience sample, a sample that is

selected based on some practical reason, which in this case was the availability of those patients with COPD who were willing to devote the time and effort to participate in this research study. Once these patients agreed to participate, they completed a one-on-one orientation with the primary investigator, which included the necessary education for successful completion of the study, in addition to the aforementioned paperwork listed above.

### **Operationally Defining the Variables**

The dependent variables of interest in this study included the quality of life of the patients with COPD, as well as their perceived dyspnea, otherwise known as shortness of breath. Quality of life was operationally defined by the COPD Assessment Test (CAT), while the perceived dyspnea was operationally defined by the Modified Medical Research Council (mMRC) Dyspnea Scale. The CAT is a scaled 8-question patient-completed questionnaire that assesses the impact of COPD (cough, sputum, dyspnea, chest tightness) on health status. The scaling system for each question consists of a score from 0-5 with a total score for the entire questionnaire ranging from 0 to 40. Higher scores denote a more severe impact of COPD on a patient's quality of life (American Thoracic Society, 2015). The mMRC Dyspnea Scale consists of five statements that describe nearly the entire range of respiratory disability from none to almost complete incapacity. This scale does not provide a quantitative value for breathlessness; rather, it quantifies the disability that is associated with breathlessness as perceived by the patient. The independent variable for this study was the IMT method that the subjects were assigned, either training via the incentive spirometer (Voldyne) or training via harmonica playing. Exercise was not a variable that was analyzed since all participants in the study were completing exercise, and thus it was considered uniform for the study. Although exercise was not considered a primary



variable of interest and was not statistically evaluated in this study, it is still important, as it is believed that a combination of therapy types is what could be most effective in improving COPD symptoms.

### **Participants**

Four individuals (1F, 3M; mean age of  $66.25 \pm 8.18$ ) with COPD completed the study as members of Group B. Members of this group were encouraged to complete low to moderate intensity exercise 3 times a week and were instructed to complete inspiratory muscle training (IMT) through the utilization of the Voldyne, a type of incentive spirometer, 3 days a week for 3 times each day, with 10 inhalations comprising each of the bouts. An incentive spirometer is a device that employs visual and other forms of positive feedback to encourage patients to maximally inflate their lungs and maintain that inflation (Basoglu, Atasever, and Bacakoglu, 2004). An incentive spirometer is used as a way to train one's inspiratory muscles and works to improve the user's inspiratory volume so that the process of respiration is enhanced. In exercising the inspiratory muscles, users have the potential to increase their lung volume and prevent fluid buildup in the lungs that is associated with a number of pulmonary conditions (Basoglu, Atasever, and Bacakoglu, 2004). The primary investigator provided education on how to properly use the Voldyne to those in Group B in order to familiarize them with the appropriate technique when using such an instrument.

The members of Group B consisted of those COPD patients currently participating in Phase III Cardiopulmonary Rehabilitation, which is a maintenance program at IU Health Ball Memorial Hospital. Although IU Health BMH does not control or provide one-on-one supervision during exercise such as in Phase II, they do still monitor the exercise participation



during this stage of rehabilitation, and Phase III patients were still encouraged to complete low to moderate intensity exercise three times a week for 40 minutes each session throughout the duration of the study. However, since it is not Standard of Care for Phase III Cardiopulmonary Rehabilitation patients to complete this exercise as a part of their specific phase of the program, this should be considered experimental in regards to this study. Members of Group B were able to complete their exercise at the Cardiopulmonary Rehabilitation facility, or elsewhere if they chose, since it is not Standard of Care. Although it was not mandated that they come to the Cardiopulmonary Rehabilitation facility to complete their exercise, it was encouraged. The use of a Voldyne is also not Standard of Care (SOC), and thus, is also considered experimental for this particular study.

Similarly, three current members (2F, 1M; mean age  $67 \pm 11.53$ ) of the Phase II Cardiopulmonary Rehabilitation at IU Health BMH diagnosed with COPD were selected as members of Group A. The responsibilities of Group A included low to moderate intensity exercise three times a week for 40 minutes each session as a part of their normal Cardiopulmonary Rehabilitation routine, with pre and post measures of vitals, such as heart rate (HR) and blood pressure (BP), in addition to harmonica training 3 times a week on non-rehab days for 30 minutes each day broken up into 3 10-minute bouts. This amount of exercise, in addition to harmonica playing, are both Standard of Care for Phase II Cardiopulmonary Rehabilitation patients at IU Health BMH, and thus, are not experimental procedures. Harmonica training, which is a part of the Phase II Cardiopulmonary Rehabilitation program at IU Health BMH, has been shown in the past to be a plausible method of inspiratory muscle training, with patients showing more compliance since it is a more enjoyable method. Since the Phase II patients that participated in this study were already completing harmonica playing as a part of

their program, they were aware of the appropriate techniques and did not necessitate education on how to properly use the harmonica. Participants for both groups were responsible for completing their form of IMT on their own time on three non-rehab days, but were checked with to make sure they remained compliant.

## **Materials**

In order to analyze the effectiveness of the Voldyne and the effectiveness of the harmonica, as well as their respective abilities to improve quality of life and perceived dyspnea as they relate to lung function, pre- and post-study surveys were issued to evaluate the progress that each individual made during the 6 weeks of training. Each participant was expected to fill out a personal journal log in order to document each of the three days during the week that they completed their inspiratory muscle training, in order to hold them accountable and also to keep them on track for their sessions. The primary investigator, in addition to the primary Cardiopulmonary Rehabilitation Specialist assisting in the study, had access to patient documentation through IU Health BMH, which included the exercise each subject was completing during the duration of the 6 weeks in which they were also completing their assigned IMT, along with information pertaining to his or her stage of COPD.

The mMRC, which is Standard of Care for each Phase II patients prior to entering the program, was used to assess each participant's breathlessness – both in Group A and in Group B – prior to the 6 weeks of inspiratory muscle training and data collection, and following the 6 weeks of training, in order to gauge each of the inspiratory training technique's effectiveness and subsequent symptom improvements from the perception of each participant. This document, although not Standard of Care for Phase III patients who comprised Group B, was necessary in



order to make comparisons between the two groups possible. Additionally, a quality of life survey, known as the COPD Assessment Test (CAT), was issued before the 6-week period of training and data collection, and then again at the conclusion of the 6-week period of training as a follow-up in order to evaluate the implications that these two modes of IMT had on each participant's quality of life. The issuing of these documents prior to and following the assigned training was necessary in order to help support the hypothesis that harmonica training has the potential to be just as effective as incentive spirometry in producing improvements in quality of life and dyspnea in patients with COPD.

## **Results**

### **Descriptive Statistics**

The COPD Assessment Test (CAT) was used to measure quality of life. Within the CAT there were 8 questions used to measure the impact that COPD has on the patient's wellbeing and daily life. Each of the 8 questions was answered along a Likert scale ranging from 0 to 5. Providing a scale for patients to respond to allows them to choose the severity of the impact that the COPD is having on that certain aspect of their life. This assessment was completed both before and after the 6-week training period.

The Modified Medical Research Council Dyspnea Scale (mMRC) was used to measure the degree of breathlessness that patients with COPD experience. The scale is a single range with 5 descriptions of breathlessness experiences that coincide with a number ranging from 0 to 5, with 5 being the worst. The primary investigator read the descriptions of the experiences to the patients beginning with the breathlessness experience that was characterized by a 5 on the scale. Participants were read each of the experiences on the scale in a sequential order, starting with 5



and working toward 0, until they answered with a “yes.” Once the participants responded with a “yes,” the primary investigator stopped, and that was the score they were assigned for their mMRC score. The participants reported their breathlessness score both before and after the 6-week training period.

Table 1 displays the mean scores and standard deviations for the CATs taken by all study participants before the 6 weeks of training and the CATs taken after the 6 weeks of training. The means and standard deviations for the pre- and post-study mMRC scores, in addition to other mean scores, can also be found in this same table. The individual response scores for the pre- and post-CATs and the pre- and post-mMRCs can be found in Table 2.

|                   | N | Minimum | Maximum | Mean    | Standard Deviation |
|-------------------|---|---------|---------|---------|--------------------|
| Age               | 7 | 56      | 79      | 66.5714 | 8.82906            |
| Ethnicity         | 7 | 1       | 2       | 1.1429  | 0.37796            |
| Gender            | 7 | 0       | 1       | 0.5714  | 0.53452            |
| COPD Stage        | 7 | 1       | 4       | 2.4286  | 1.13389            |
| Pre-CAT           | 7 | 11      | 27      | 17.4286 | 5.68205            |
| Post-CAT          | 7 | 6       | 24      | 16.4286 | 6.21442            |
| Pre-mMRC          | 7 | 1       | 3       | 2.1429  | 0.69007            |
| Post-mMRC         | 7 | 1       | 3       | 1.2857  | 0.75593            |
| CAT Change Score  | 7 | -0.38   | 2       | 0.2771  | 0.83356            |
| mMRC Change Score | 7 | 0       | 3       | 1       | 1                  |

Table 1. Descriptive statistics for all 7 study participants

| Participant | Group   | pre-mMRC | post-mMRC | pre-CAT | post-CAT |
|-------------|---------|----------|-----------|---------|----------|
| 1           | Group B | 2        | 11        | 1       | 11       |
| 2           | Group B | 2        | 13        | 2       | 21       |
| 3           | Group B | 3        | 18        | 3       | 24       |
| 4           | Group A | 3        | 18        | 1       | 6        |
| 5           | Group A | 2        | 27        | 1       | 19       |
| 6           | Group B | 2        | 22        | 1       | 15       |
| 7           | Group A | 2        | 22        | 1       | 15       |

Table 2. Individual descriptive statistics for the pre- and post-study measurements



### Inferential Statistics

In order to determine if the entire group of participants improved from the beginning of training comparative to after training, the collected pre-measures for the CAT and mMRC were compared to their respective post-measures for the group as a whole using a paired samples t-test. Also called a dependent t-test, a paired-samples t-test compares the means between two related groups on the same, continuous dependent variable. In the case of this study, the two “related groups” was the individual’s score before the study and the individual’s score after the study. The paired-samples t-test was used to compare the two means, or two scores, from the same study subject. This test is useful when evaluating participants on their pre- and post-measures with an intervention between the two time points, which in this case would be the 6-week training period of IMT. The purpose of a paired-samples t-test is to determine if there is statistical evidence that the mean difference between the paired observations on a specific outcome is significantly different from zero. Table 3 shows the results of these two comparisons.

| Paired-Samples t-Test |         |                |                 |
|-----------------------|---------|----------------|-----------------|
| pre-CAT – post-CAT    |         |                |                 |
| Paired Differences    |         |                |                 |
| N                     | Mean    | Std. Deviation | Sig. Difference |
| 7                     | 0.85714 | 0.69007        | 0.017*          |
| pre-mMRC – post-mMRC  |         |                |                 |
| Paired Differences    |         |                |                 |
| N                     | Mean    | Std. Deviation | Sig. Difference |
| 7                     | 1       | 8.02081        | 0.753           |

**Table 3.** A representation of the paired-samples t-test ran to evaluate any differences between pre- and post-measures for the entire group of participants. The mean value is the difference between the mean score for the pre-measure and the mean score for the post-measure. These means can be found in Table 1. The standard deviation value represents the deviation of the difference between the pre- and post-measures.

\* = significant difference ( $p < 0.05$ )



One of the objectives of this study was to determine if harmonica playing was a feasible way to administer inspiratory muscle training to those COPD patients who suffer from inspiratory muscle weakness, which could be contributing to their dyspnea or affecting their quality of life, and whether harmonica was as effective as IMT administered through an incentive spirometer. In order to determine any post-training differences between Group A, who utilized the harmonica, and Group B, who utilized the Voldyne, the two groups were analyzed separately to help conclude if one group improved more than the other, or if both groups experienced similar results and benefits from participating in inspiratory muscle training. Table 4 contains the results of the two paired-samples t-tests that were conducted on each of the two groups.

| Paired Samples Statistics                |   |        |                |                 |
|--|---|--------|----------------|-----------------|
| Group A (Harmonica Training)             |   |        |                |                 |
| Paired Differences                       |   |        |                |                 |
|  | N | Mean   | Std. Deviation | Sig. Difference |
| pre-CAT                                  | 3 | 22.333 | 4.50925        | 0.028*          |
| post-CAT                                 | 3 | 13.333 | 6.65833        |                 |
| Paired Differences                       |   |        |                |                 |
|  | N | Mean   | Std. Deviation | Sig. Difference |
| pre-mMRC                                 | 3 | 2.3333 | 0.57735        | 0.057           |
| post-mMRC                                | 3 | 1      | 0              |                 |
| Group B (Incentive Spirometry – Voldyne) |   |        |                |                 |
| Paired Differences                       |   |        |                |                 |
|  | N | Mean   | Std. Deviation | Sig. Difference |
| pre-CAT                                  | 4 | 13.75  | 2.98608        | 0.063           |
| post-CAT                                 | 4 | 18.75  | 5.56028        |                 |
| Paired Differences                       |   |        |                |                 |
|  | N | Mean   | Std. Deviation | Sig. Difference |
| pre-mMRC                                 | 4 | 2      | 0.8165         | 0.391           |
| post-mMRC                                | 4 | 1.75   | 0.95743        |                 |

**Table 4.** Results for the paired-samples t-tests conducted to distinguish any pre-post differences in the two groups of participants

\* = significant difference ( $p < 0.05$ )



From the paired samples t-test, it was determined that Group A improved on the mMRC reports from pre to post, and improved significantly from their pre-CAT to post-CAT measures. It was also revealed that Group B improved on their mMRC from pre to post, but did not improve on the CAT after the 6-week training period, but in fact reported worse scores on their post-CAT measure. Finally, an independent samples t-test was conducted as a way to evaluate the change scores for each group to determine the degree of change of each group's CAT and mMRC scores from before to after the training period. A change score is just a simple way to quantify the difference in scores from pre to post. An independent samples t-test was run for both the CAT and the mMRC scores. The results of these tests can be found in Table 5.

| Independent Samples T-test Statistics |               |   |                   |                |        |
|---------------------------------------|---------------|---|-------------------|----------------|--------|
|                                       | Group         | N | Mean Change Score | Std. Deviation | Sig.   |
| mMRC                                  | A (Harmonica) | 3 | 1.3333            | 0.57735        | 0.045* |
|                                       | B (Voldyne)   | 4 | 0.25              | 0.5            |        |
| CAT                                   | A (Harmonica) | 3 | 9.0               | 2.64575        | 0.002* |
|                                       | B (Voldyne)   | 4 | -5.0              | 3.4641         |        |

**Table 5.** Results of the independent t-tests run to evaluate the degree of change in pre to post measures for the mMRC and CAT for both Group A and Group B

\* = significant difference ( $p < 0.05$ )

## Discussion

### The Statistical Data

The purpose of this study was to assess if and what effect harmonica playing as a form of IMT has on perceived dyspnea and quality of life of those patients with COPD and if it would be worthwhile to include such a therapy as an adjunct to traditional Pulmonary Rehabilitation (PR) programs. Various statistical tests were conducted in order to evaluate the relationships between the IMT types and their affect on the variables of interest, which were dyspnea and quality of life. These tests included two paired samples t-tests and an independent samples t-test. The



resulting p-value from each test was used in order to determine if there was significant change from before to after the 6-week inspiratory muscle training intervention. The p-value is the probability of finding the observed results when the null hypothesis, or the proposed hypothesis, of the study question is true. When a p-value is less than 0.05, this indicates that the results that were found were significant and that the null hypothesis was found to be true.

### **Paired Samples t-Test for the Entire Sample**

Results from the paired samples t-tests that were used to evaluate changes in the entire group revealed that the group as a whole experienced a significant improvement in shortness of breath ( $p = 0.017$ ), regardless of the type of IMT they were completing. The results also indicated that the group as a whole did not experience a significant improvement in quality of life ( $p = 0.753$ ). The results of this statistical test were a little surprising, as it was anticipated that the group as a whole would improve significantly in terms of perceived dyspnea and quality of life with exercise and the addition of some type of inspiratory muscle training. When a test like this is run on an entire group that consisted of two subgroups that were participating in different training types, it is important to evaluate the groups individually as well in order to pinpoint any influence that could have altered the expected results. Subsequently, that is why the groups were evaluated separately using pre-post measures via the paired samples t-test and also with the independent samples t-test, which was used to compare change scores in order to provide an impression of the degree of change between the pre- and post-measures once the training period was complete.



**Paired Samples t-Test for Individual Groups' Pre-Post Measures**

The results for the paired samples t-test that evaluated Group A's pre- and post-measures showed a significant improvement ( $p = 0.028$ ) from the pre-CAT score to the post-CAT score. This value suggests that Group A, who played the harmonica and exercised on a weekly basis during the 6-week training period, experienced a significant improvement in quality of life. The significance value for the pre-post measure for the mMRC for Group A was  $p=0.057$ . This value was not quite significant, but it was very close, as significance is defined by a p-value less than 0.05. Even though this value was not significant, there was a clear improvement on the post-mMRC when compared to the pre-mMRC for this group from a mean pre-measure of 2.333 to a mean post-measure of 1. The paired samples t-test for Group B, the group utilizing the Voldyne, had p-values of 0.063 and 0.391 for the pre-post measures for the CAT and mMRC, respectively. Since the mean difference between the pre- and post-CAT surveys for this group was -5.0, this indicates that the group actually declined on their scores for quality of life after the 6 weeks of IMT, and the p-value of 0.063 suggests that the post-measures for the CAT were nearly significantly worse when compared to the pre-measures for the CAT for Group B. The mMRC for Group B, however, did improve, but only by 0.25 from pre to post, so there was no significant improvement ( $p = 0.391$ ).

**The Independent Samples t-Test Evaluating Change Scores**

The independent samples t-test that was conducted was important in the evaluation of the degree of change of pre-post measures in Group A and Group B. It was made clear from the paired-samples t-tests that both groups experienced changes in their pre- and post-measures, but a change score allows for the determination of the severity of change and if one group changed



more than the other. The independent samples t-test produced a significance value of  $p=0.045$  for the mMRC and a significance value of  $p=0.002$  for the CAT. These significance values represent comparisons between the changes in the two groups. The significance values obtained through these tests indicate that Group A, who played the harmonica as their form of IMT, improved significantly more in terms of both perceived dyspnea and quality of life than Group B did. Between this test result and the results of the paired-samples t-tests, it can be concluded that harmonica training is, in the case of this study, more effective in improving perceived shortness of breath and quality of life than an incentive spirometer. The findings help support the hypothesis that harmonica playing, when combined with exercise, can serve as an effective form of IMT for patients with COPD.

### **Obstacles for the Current Research**

Although the results of the current research were favorable for the most part, some limitations to this study must be addressed in order to recognize some shortcomings that may have influenced the results. The issue of subjects dropping out of the study poses a problem for the interpretation of the results. With such a small sample size, it is difficult to make a conclusive judgment on the reliability and true significance of what was found, even though there were clear improvements in certain variables and definitive significant differences were found. Such a small sample size makes it difficult to extrapolate the results to a larger population, and since the sample consisted of only COPD patients, the results can only be generalized to COPD patients, not the general public, which is something to consider. The sample size was not only small, but it was also a convenience sample, one that was selected based on availability of those patients



willing to participate. A convenience sample has limitations in terms of the ability to extrapolate the results because it is not the truest representation of the larger population.

Additionally, the issue of incompleteness of the 6 weeks of training by half of the sample presents an obstacle for home-based harmonica playing as a component of a comprehensive Pulmonary Rehabilitation program. Factors that contribute to the motivation to participate in harmonica training and to continue with harmonica training are both important factors to consider. For example, some patients at the time of recruitment were not interested in harmonica playing and did not really understand the point of doing it even after some of the research that has been done on its benefits for patients with obstructive pulmonary conditions was explained. Such a response came as a surprise because the opportunity to improve one's health and increase the ease with which the individual is able to complete daily tasks seems like reason enough to at least try a new, prospective therapeutic modality.

Another limitation to the study is the fact that subjects had to self-report their harmonica playing or Voldyne repetitions. The primary investigator was not present to monitor study participants, so the participants were held accountable for their assigned IMT. There is no way to prove or ensure that the participants were actually doing what they were instructed to do. Patients may not have completed the full duration or frequency that they were supposed to do simply because of the unreliable nature of self-report. Likewise, there may have been some evaluation apprehension associated with the method of self-report. Evaluation apprehension is a type of reactivity in research where subjects are concerned about the impression they leave with the experimenter and what the experimenter will think of them. It was difficult to distance the subject and experimenter due to the need for pre- and post-test evaluations. As a result, it is possible that there could have been potential for members of Group A to report greater playing



time to appease the primary investigator. Similarly, members of Group B might have reported higher volumes achieved during their incentive spirometer repetitions.

A final major limitation to this study was the limited amount of time to pursue long-term effects of the observed interventions. Looking at the long-term effects could have yielded different results, so this is something to consider. It remains in question as to which one of the two techniques evaluated produces a more permanent effect on pulmonary function and reduces exacerbation of symptoms when used for an extended period of time.

### **The Feasibility of IMT as an Adjunct Therapy**

In order to understand the potential of harmonica as a form of IMT, it is important to first understand the feasibility of using IMT, in any form, as an adjunct therapy in a traditional Pulmonary Rehabilitation program. The rationale for including IMT as a component of PR is still under debate. Likewise, the inclusion of IMT as a part of rehab programs for COPD is questioned. These uncertainties may be attributed to two misconceptions. The first misconception is that the diaphragm of patients with COPD is already well trained (Magadle, et al., 2007). The adaptations of endurance, however, are also associated with a loss of type 2 muscle fibers, an event that could contribute to the simultaneous loss of muscle strength that is seen (Magadle, et al., 2007). Loss of inspiratory muscle strength leads to negative sensory implications for exertional dyspnea. This results from the requirement of the muscle to act at a mechanical disadvantage due to hyperinflation (Magadle, et al., 2007). Therefore, the patients with COPD do not have inspiratory muscles that are well trained; they are simply adapted to the required increase in pressure generation during breathing at rest. The second misconception is that general exercise reconditioning is sufficient enough to provide a training stimulus capable of



yielding improvements in inspiratory muscle strength, and that the addition of IMT is therefore redundant, but there is plenty of data to support the contrary.

Quality of life and shortness of breath are undoubtedly the most valuable outcomes from a patient's perspective (Magadle, et al., 2007). Improvements in these characteristics could alone be enough to justify the incorporation of IMT into PR programs. An increase in inspiratory muscle strength and endurance could reduce symptoms and improve functional capacity in those with severe COPD, regardless of an improvement in airway obstruction. Basoglu et al. (2004) reports from their own study that assessed the implications of incentive spirometry on those individuals with severe COPD, that health-related quality of life improved in the group that underwent incentive spirometry, while the control group that only underwent medical treatment showed no significant change following the 2 months of treatment. They also reference a meta-analysis that found that IMT alone significantly improved inspiratory muscle strength and endurance in patients with COPD, while dyspnea decreased significantly in these patients. An additional study conducted by Tirway et al., found a substantial improvement in subjective reports of well-being and breathlessness with the use of spirometry in patients with COPD. These subjective findings reflect an enhanced quality of life as reported in this study.

In a meta-analysis conducted by Gosselink et al. (2011) on the effects of IMT in patients with COPD, significant improvements were found in maximal inspiratory muscle strength, endurance time, 6- or 12-minute walking distance, and quality of life, and dyspnea was significantly reduced. IMT added to a general exercise program significantly improved maximal inspiratory strength, and functional exercise capacity exhibited a tendency to increase in those who experience inspiratory muscle weakness (Gosselink, et al., 2011). This study demonstrated the ability of IMT to improve inspiratory muscle strength and endurance, functional exercise

capacity, dyspnea, and quality of life, and that the addition of IMT to exercise for patients with inspiratory muscle weakness has the ability to improve exercise performance. The improvement in inspiratory muscle endurance capacity could be attributed to a significant increase in the proportion of type I fibers, which are the muscle fiber type with the greatest endurance capacity, and the size of type II fibers in the external intercostal muscles following IMT (Gosselink, et al., 2011). The conclusion from this study is that IMT is an effective treatment modality in COPD patients in the respect that it can assist in improving respiratory muscle strength and endurance, producing reductions in dyspnea and improvements in functional exercise capacity and health-related quality of life, and those patients with more advanced muscle weakness appear to respond better to the intervention, especially when considering the combination of IMT and exercise training (Gosselink et al., 2011).

In a meta-analysis performed by Lötters et al. (2002) that had the objective of reviewing studies that investigated the efficacy of IMT in patients with COPD, it was discovered, after reviewing 15 studies, that inspiratory muscle training alone and inspiratory muscle training included as an adjunct to general exercise reconditioning both significantly increased inspiratory muscle strength and endurance. It was also found that this type of training had a significant effect on dyspnea both at rest and during exercise for those who suffer from COPD. Additionally, it was revealed that the combination of IMT and exercise had a more profound impact on those patients with inspiratory muscle weakness, as they improved significantly more than those patients who lacked inspiratory muscle weakness (Lötters et al., 2002). From this, it is suffice to say that inspiratory muscle training can serve as an important component to a Pulmonary Rehabilitation program that specifically targets COPD patients with inspiratory muscle weakness. Analyzing inspiratory muscle weakness through the measuring of maximal inspiratory



pressure ( $PI_{max}$ ) would reflect the strength of the diaphragm, the primary muscle used during inspiration, and other inspiratory muscles. Collecting this sort of measurement could help reveal a patient's vulnerability and assist in determining a patient's need for, and possible benefits from, a training modality like IMT. Adding IMT to a COPD patient's Pulmonary Rehabilitation program, especially those with inspiratory muscle weakness, could help yield favorable results in terms of quality of life and the ease with which they complete activities of daily living, in addition to shortness of breath and other common side effects of this obstructive lung disease. It is imperative that pulmonary rehabilitation programs' staff and faculty are made aware of the implications that these tools can have on their patients' prognoses and well-being.

### **The Rationale for Utilizing Harmonica Playing as a Type of IMT**

Alexander and Wagner (2012) performed a study that analyzed the use of harmonica training in conjunction with exercise conditioning. Exercise conditioning consisted of a frequency of two times a week for 8-10 weeks for a total of 16 sessions. The study consisted of a control group, which participated in a traditional pulmonary rehabilitation (PR) program, and a harmonica-training (HT) group, which participated in the traditional PR program with the addition of harmonica training. After orientation to PR, patients who were randomly chosen to participate in the HT group were given a harmonica and completed 15 minutes of one-on-one instruction with a member of the PR staff. Following this 15 minute session, patients were expected to perform for at least 5, but no more than 20, minutes twice per day, for a total of 10-40 minutes each day on 5 days of the week (Alexander and Wagner, 2012).

Once the therapy sessions were complete, the control and experimental groups were evaluated using a statistical analysis. Despite the many accounts from COPD patients and their

healthcare providers who attest to its beneficial effects, adding harmonica playing to a traditional PR program did not prove to be any more beneficial than the traditional PR program alone (Alexander and Wagner, 2012). The results also revealed that, although there have been suggestions that harmonica playing can serve as a similarly effective therapy for improving breathing as inspiratory muscle training, harmonica playing did not produce improvements in inspiratory muscle strength and functional capacity like IMT combined with exercise training has previously (Alexander and Wagner, 2012).

Despite the lack of significant difference in Alexander and Wagner's study, it was discovered that the subjects as a whole showed significant improvements in a handful of imperative outcome measures that demonstrate the influence of a multidisciplinary, comprehensive PR program. Patient perception of dyspnea indeed decreased significantly from baseline measures that were collected using the University of California at San Diego Shortness of Breath Questionnaire (SOBQ), a tool that assesses the level of breathlessness experienced during activities of daily living, such as doing laundry, vacuuming, and showering (Alexander and Wagner, 2012). Additionally, the patients' health-related quality of life improved due to participation in Pulmonary Rehabilitation. There is not a lot of objective evidence supporting a specific harmonic playing prescription, so it would be helpful in the future to investigate a more concrete time and frequency of play that is capable of eliciting a beneficial response.

John Schaman, an M.D. from Canada, has been a pioneer in the research evaluating the efficacy of harmonica training for individuals with pulmonary conditions. He conducted a study to determine if pulmonary exercises could reduce the loss of lung function. The respiratory "tool" chosen for his study was the diatonic harmonica, as it is the only instrument that "makes music" with blowing and drawing of air. He, along with harmonica experts, spent a substantial



amount of time devising an effective “harmonica method,” which involves rhythmic chordal playing. The primary objectives of H.E.L.P., or the Harmonica Exercise for Lung Program, are strengthening respiratory muscles, including the diaphragm, exercising the lungs above their “comfort zone” in the inspiratory range, and exercising the lungs below the “comfort zone” in the expiratory range (“Oxygen for the Soul,” n.d.).

Schaman found that harmonica musicians and opera singers who use their lungs in an extraordinary way do not seem to experience the normal excessive loss of lung capacity and function that is associated with aging, when has been suggested to be attributed to the requirement of breathing in and out while playing the harmonica, providing the lungs and the diaphragm with a natural workout (“Oxygen for the Soul,” n.d.). This same knowledge and common sense can be applied in a practical way to hospitals and rehab programs in the treatment of terminally ill lung patients, such as those who suffer from COPD, through the application of harmonica therapy. In 2007, Schaman began his study of the potentials of harmonica therapy as a way to deter lung deterioration and discovered that the playing of simple melodies was not providing a sufficient workout for the respiratory muscles, and so he switched to rhythmic playing, which succeeded in meeting the expectations for the workout aspect, but pretty much excluded musicality. Thus, Schaman developed his own technique known as chordal jamming. With this technique, patients had the ability to play multiple notes using the two chords that can be found on the traditional harmonica, which requires the use of more air, providing patients with a better and more worthwhile workout for their lungs. Schaman still was not completely satisfied, so with a lot of trial and error came the creation of the HarmonicaMD “Medical Harmonica,” a harmonica that could play eight chords and was easier to use (“Oxygen for the Soul,” n.d.).



A similar innovation in the experimentation of harmonica therapy is the Pulmonica. This harmonica is a strategically designed and tuned pulmonary harmonica that is unique in its own right through its production of deep, resonant, meditative sounds that vibrate within the lungs and sinuses to help facilitate better breathing. These pulses move deep within the lungs and help loosen secretions that can then be eliminated. Once the secretions are coughed up, breathing becomes easier for the individual ("Pulmonica" Research Results, 2013). These claims are supported by a study in 2013 titled "A COPD Support Group Using a Novel Harmonica Device" that was supervised by Dr. William Weiss, who has served as the pulmonologist at Senior Friendship Center for 18 years. All study participants had Stage 3 COPD without other serious comorbidities (i.e. congestive heart failure). Nine COPD patients completed the pulmonary rehab study. The study consisted of spirometry, 6-minute walk and quality of life assessments, the teaching of proper breathing techniques and use of medications, a brief exercise program that included stretching, hand weights, and chair exercises, and the use of the Pulmonica Pulmonary Harmonica. Everyone who participated improved in his or her quality of life assessment, spirometry, 6-minute walk test, and there was a general consensus met that the more the Pulmonica was played, the better the patients breathed and felt ("Pulmonica" Research Results, 2013). The qualitative findings were highly significant and demonstrated that the more people played the Pulmonica, the better they could breathe, the clearer their lungs were, the more energy they had, and the better they felt. Patients made numerous testimonies, claiming decreased auxiliary oxygen, inhaler, and nebulizer use, better sleep, walking further, feeling calmer because of a meditative aspect of playing, and more ("Pulmonica" Research Results, 2013).

Although the research on the effectiveness and benefits of harmonica playing for those with COPD has been limited, these two studies indicate that there are medical professionals who



are inquiring about the advantages that harmonica playing can have on pulmonary muscle wasting and inspiratory muscle weakness, especially in those individuals who struggle with a pulmonary condition like COPD. These two research studies, and the current research study, serve as a gateway to future research that can help establish the utilization, and subsequent efficacy of, harmonica training as a component of a standard Pulmonary Rehabilitation program.

### **Considerations for Future Research**

It is always important to consider potential improvements in research methods that could produce better results in future studies. In future endeavors, random selection and random assignment could provide a more homogenous sample. The convenience sample used for this study could be responsible for some disparities in the two subgroups, which may or may not be responsible for the dissimilarities in results for Group A and Group B. It would also be ideal to have a larger sample size in a study like this in order to have a broader profile of age, COPD stage, and additional notable characteristics. Additionally, prescribed oxygen, medications, and other medicinal combinations are characteristics that should be taken into consideration in future research and how these may or may not affect the results, as it is likely that these extraneous variables could have limited the results of this study.

The current research looked at only harmonica playing in those individuals with COPD. It may be useful to analyze the implications of harmonica playing for other obstructive lung diseases such as asthma. It may also be interesting and worthwhile to investigate how harmonica playing, and other IMT, influences restrictive lung diseases, such as pulmonary fibrosis, neuromuscular conditions, and other interstitial lung diseases.



Further research to support the benefits of harmonica playing as a method of IMT in addition to patient education on those positive outcomes will be important to compliance. Group participation in harmonica playing may also help improve compliance as it could serve as way to motivate one another and hold each other accountable. If there are social ties associated with this type of therapeutic modality, this may provide some encouragement that is linked to a common interest and common experience that could help to improve retention. Future research could analyze compliance and improvements associated with group harmonica playing versus individual harmonica playing to determine if one is more beneficial than the other in terms of retention and subsequent improvements in perceived symptoms. Although the only evidence to really support the use of harmonica playing as an adjunct therapy to a traditional Pulmonary Rehabilitation program is testimonies of patients, harmonica playing is a fun and interactive way to train the inspiratory muscles of those who suffer from COPD. It is important to consider other creative ways to assist patients in improving breathing dynamics, and harmonica playing may be a feasible and enjoyable way of accomplishing this.

### **The Current Research's Conclusions**

Lötters et al. (2002) found that in the only two studies from the subgroup that measured dyspnea, neither found a significant decrease in dyspnea following IMT, which could be attributed to the high baseline maximal inspiratory pressure, which is a reflection of the strength of the diaphragm and other inspiratory muscles, suggesting that inspiratory muscle performance was likely not primarily responsible for the dyspnea experienced by these patients. Similarly, there was no significant improvement in dyspnea in the COPD patients involved in the present study, as identified by the mMRC documents that participants completed prior to and after the 6



weeks of IMT. The group that was the closest to achieving a significant improvement was Group A, the group that played the harmonica, which had a p-value of 0.057 on the paired-samples t-test that evaluated the groups separately on their pre-post measures. This could help support the idea that IMT tends to be more effective in those patients with more severe inspiratory muscle weakness, giving future research a possible direction to head toward in the selection of research participants for effective and worthwhile findings.

It has traditionally been believed that COPD is a progressive disease characterized by a constant increase in symptoms, but recent evidence has challenged this paradigm; rather it has been pointed out that patients do not consistently perceive COPD-related symptoms in the same way. Not only are there seasonal variations, but symptoms also seem to change, in the perception of the patient; during a week or even within a single day (Lopez-Campos, Calero, and Quintana-Gallego, 2013). In the current study, the methods utilized to determine improvements in COPD symptoms were two questionnaires, one that pertained to breathlessness, and one that consisted of questions related to other COPD symptoms and their influence on quality of life. In the cases where the post-measures did not improve in comparison to the pre-measures, it could be that the patients were experiencing exacerbations that day or simply perceived their symptoms to be worse than they were when they took the questionnaire before the 6 weeks of IMT. According to the available data, patients experience the largest increase in respiratory symptoms early in the morning, followed by nighttime (Lopez-Campos et al., 2013). Therefore, the current study should have controlled for the time in which the patients evaluated their symptoms so that they were consistent as far as when they were assessing themselves. Additionally, it is likely that simply using subjective reports of measures is not a sufficient way to compare pre- and post-measures in such a situation. It may be worthwhile to incorporate a measure of forced vital

capacity in 1 second ( $FEV_1$ ), which is a measurement of the maximal amount of air one can force out of his or her lungs during the first second of a forced exhalation. Collecting this measure before and after the training period in addition to a questionnaire that gauges symptom variability throughout the day may be necessary in order to determine changes in lung function.

In summary, it can be claimed from the present study that harmonica training, as a form of inspiratory muscle training, can significantly improve the quality of life in patients with moderate to severe COPD, and, although not quite significantly, can also improve shortness of breath. From the results, it is concluded that harmonica training improved quality of life and perceived dyspnea significantly more than the Voldyne was able to accomplish. The results do not show a clear improvement or regression in terms of COPD symptoms, other than the enhanced quality of life of those participants who played the harmonica. Conducting a similar study with a larger sample size and measures of inspiratory muscle strength, forced expiratory volume in one second, and forced vitality capacity, may produce more concrete results and provide stronger evidence in support of the inclusion of harmonica training in a comprehensive Pulmonary Rehabilitation program. The simplicity of the harmonica is what makes its utilization so attractive; it is a relatively uncomplicated device that can be easily used at the patient's bedside for IMT. It is worthwhile to continue to research and to consider the use of harmonica playing as a component of routine rehabilitation protocol for those patients with COPD.



### References

- Alexander, J. L., PhD, & Wagner, C. L. (2012). Is harmonica training an effective adjunct therapy to pulmonary rehabilitation? *Rehabilitation Nursing, 37*(4), 207-212.
- Ambrosino, N. (2011). The case for inspiratory muscle training in COPD. *European Respiratory Journal, 37*, 233-235.
- Basoglu, O. K., Atasever, A., & Bacakoglu, F. (2005). The efficacy of incentive spirometry in patients with COPD. *Respirology, 10*, 349-353.
- Celli, B., MacNee, W., Augusti, A., Berg, B., Rennard, S., & Murris, J. (2004). Standards for diagnosis and treatment of patients with COPD: A summary of the ATS/ERS position paper. *European Respiratory Journal, 23*, 932-946.
- Definition of Standard of Care. (2012, June 14). Retrieved January 22, 2016, from <http://www.medicinenet.com/script/main/art.asp?articlekey=33263>
- Gosselink, R., De Vos, J., Van den Heuvel, S. P., Segers, J., Decramer, M., & Kwakkel, G. (2011). Impact of inspiratory muscle training in patients with COPD: What is the evidence? *European Respiratory Journal, 37*, 416-425.
- Heydari, A., PhD, Farzad, M., MSN, & Ahmadi hosseini, S., MD. (2013). Comparing inspiratory resistive training with incentive spirometry on rehabilitation of COPD patients. *Rehabilitation Nursing, 0*, 1-6.
- Larson, J. L., Kim, M. J., Sharp, J. T., & Larson, D. A. (1988). Inspiratory muscle training with a pressure threshold breathing device in patients with chronic obstructive pulmonary disease. *American Review of Respiratory Disease, 138*, 689-696.
- Lopez-Campos, J. L., Calero, C., & Quintana-Gallego, E. (2013). Symptom variability in COPD: A narrative review. *International Journal of COPD, 8*, 231-238.

- Lötters, F., Van Tol, B., Kwakkel, G., & Gosselink, R. (2002). Effects of controlled inspiratory muscle training in patients with COPD: A meta-analysis. *European Respiratory Journal*, 20, 570-576.
- Magadle, R., McConnell, A. K., Beckerman, M., & Weiner, P. (2007). Inspiratory muscle training in pulmonary rehabilitation program in COPD patients. *Journal of Respiratory Medicine*, 101(7), 1500-1505.
- Oxygen for the Soul. (2014). *Innovators*, 24-25.
- Pulmonica Research Results. (2013). Retrieved 2016, from <http://www.pulmonica.com/Research.htm>
- Rennard, S. I., & Stoner, J. A. (2005). Challenges and opportunities for combination therapies in chronic obstructive pulmonary disease. *Proceedings of the American Thoracic Society*, 2, 391-393.
- Rodriguez-Roisin, R. (2000). Toward a consensus definition for COPD exacerbations. *Chest*, 117, 398-401.



## **APPENDIX A: Institutional Review Board (IRB) Documents**



# Ball Memorial Hospital

## Institutional Review Board

DATE: June 18, 2015

TO: Allyson Garrett

FROM: IU Health Ball Memorial Hospital IRB

PROJECT TITLE: [754903-1] Assessment of Unique Inspiratory Muscle Training Techniques Utilized by Patients with COPD

REFERENCE #: #15-953

SUBMISSION TYPE: New Project

PROJECT STATUS: Active

ACTION: APPROVAL

DECISION DATE: June 17, 2015

EXPIRATION DATE: June 16, 2016

REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review categories #4 & #7

The IU Health Ball Memorial Hospital Institutional Review Board has voted to approve your New Project, effective June 17, 2015 through June 16, 2016.

The following is a list of documents reviewed:

- Application Form - New Protocol Submission Form
- Confidentiality/Non-Disclosure - Confidentiality Agreement for PI
- Consent Form - Consent/HIPAA for Group A Members
- Consent Form - Consent/HIPAA for Group B Members
- Data Collection - Data Sheet
- Other - Exercise Log Sheet
- Other - Assurance Agreement for PI
- Other - Expedited Review Checklist
- Other - Activity Log Sheet for Participants
- Other - Flyer for Participant Recruitment (Group A)
- Other - Flyer For Participant Recruitment (Group B)
- Proposal - Thesis Proposal
- Questionnaire/Survey - Modified Medical Research Council Dyspnea Scale (mMRC Breathlessness Scale)



- Questionnaire/Survey - COPD Assessment Test (CAT)
- Training/Certification - Conflict of Interest/CITI/Resume

Please note it is the responsibility of the principal investigator to notify the IRB promptly of:

- any revisions to previously approved materials prior to initiation
- any unanticipated problems involving risks to subjects or others (UPIRSOs)
- any serious and unexpected adverse events involving local subjects and/or related or probably related to the research
- any non-compliance issues or complaints regarding this project
- when the project is completed or discontinued

This project has been determined to be a Minimal Risk project. Based on the risks, this project requires continuing review by this committee on an annual basis. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of June 16, 2016.

It is your responsibility as the Principal Investigator to ensure that strict confidentiality of patient information, research data, and any materials used to gather data is maintained by all persons associated with this research project. Violation of confidentiality will result in termination of this study and could lead to legal and/or civil penalties.

Please note that all research records must be retained for a minimum of three years after the completion of the project. Additional requirements may apply.

Any notifications should be submitted to the IRB electronically using the appropriate forms. If you have any questions, please contact Alfreda Bright at (765) 747-8458 or [abright@iuhealth.org](mailto:abright@iuhealth.org). Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within IU Health Ball Memorial Hospital IRB's records.



Indiana University Health Ball Memorial Hospital  
Institutional Review Board (IRB)

## ASSURANCE AGREEMENT FOR INVESTIGATORS

|                         |  |       |           |
|-------------------------|--|-------|-----------|
| IRBNet ID Number:       | 754903-1   | Date: | 5/22/2015 |
| Principal Investigator: | Allyson Garrett  |       |           |
| Study Title:            | Assessment of Unique Inspiratory Muscle Training Techniques Utilized by Patients with COPD |       |           |

I hereby give assurance that I will comply with the federal regulations for the Protection of Human Research Subjects of the Department of Health and Human Services (HHS), the Food and Drug Administration (when applicable), and the Institutional Review Board (IRB) of IU Health Ball Memorial Hospital. I further agree to the following statements:

- A. The proposed research project will be conducted by me or under my direct supervision.
- B. No human being will be involved as a research subject unless an informed consent form has been explained and signed. The informed consent document must be IRB approved. (The exception is an IRB approved study with exempt status.)
- C. A date-stamped copy of the original IRB approved informed consent form will be kept in the IRB Office. This is the only version of the consent form that may be used to enroll participants.
- D. Continuing review and re-approval will be conducted no less than annually as determined by the IRB. The required information and forms, as requested by the IRB, will be submitted prior to expiration of the approval. The study will be suspended (including enrollment of subjects) if continuing review is not submitted in time for re-approval.
- E. Reports of death, injuries, or unanticipated problems involving risks to research subjects will be promptly reported to the IRB.
- F. The protocol, as approved by the IRB, will be strictly adhered to. Any amendments, revisions or changes must be approved by the IRB before implementation except to eliminate an immediate hazard to participants. Any deviation from the protocol is considered an amendment and must be reported, along with the rationale, to the IRB for approval as soon as possible.
- G. The IRB shall have the authority to suspend or terminate approval of the research project if the study is not conducted in accordance with the IRB's conditions, decisions and requirements.
- H. It is the responsibility of the Principal Investigator to ensure that strict confidentiality of patient information, research data and any materials used to gather data be maintained by all persons associated with this research project. Violation of confidentiality will result in termination of this study and could lead to legal and/or civil penalties.
- I. A final report (after data analysis is complete) will be submitted to the IRB as soon as it is available.

**This form must be electronically signed within IRBNet by the Principal Investigator. Your electronic signature indicates you agree to the terms stated above.**





Indiana University Health Ball Memorial Hospital, Inc.  
Institutional Review Board (IRB)

## CONFIDENTIALITY AGREEMENT

|                         |   |       |           |
|-------------------------|---|-------|-----------|
| IRBNet ID Number:       | 754903-1  | Date: | 5/22/2015 |
| Principal Investigator: | Allyson Garrett   |       |           |
| Study Title:            | Assessment of Unique Inspiratory Muscle Training Techniques<br>Utilized by Patients with COPD |       |           |

I have read and agree to adhere to the following conditions of this confidentiality agreement.

- I understand the confidential nature of the medical information and personally identifiable information that I shall have access to while collecting data pertaining to the aforementioned research project.
- I understand that "personally identifiable information" is defined as any information that might help someone identify a specific person (e.g., name, birth date, admission date, discharge date, date of death, address, Social Security Number, telephone number, medical record number, health insurance policy number, spouse's name, employer's name, occupation, photographs, etc.).
- I shall exercise my best efforts to protect the confidentiality of any medical and/or demographic information that I may be granted access to pertaining to the aforementioned research project. Furthermore, I also understand that I have a legal duty to exercise my best efforts to protect the privacy of any individual who has received medical care/services at any Indiana University Health Ball Memorial Hospital, Inc. facility.
- In the course of conducting the aforementioned research project, I acknowledge and agree that I shall exercise my best efforts to preserve the anonymity of the research subjects.
- I shall report and publish my research findings and conclusions in a manner that does not permit identification of the patients whose records were reviewed in the course of the research project.
- Research reports and publications shall not contain any personally identifiable information, photographs, or visual representations maintained in the medical records.
- I will not disclose the medical information or medical records in individually-identifiable form to any other individual. I also agree that I shall not use such information for my own personal advantage or for the advantage of a third party.
- I acknowledge and agree that if I fail to comply with any of the terms of this Confidentiality Agreement, the Institutional Review Board has the right to take such action as it deems appropriate, including termination of the research project. I also acknowledge and agree that failure to comply with the terms of this Confidentiality Agreement may lead to other disciplinary or legal action. If the research project is terminated, I shall immediately relinquish any and all information pertaining to the research project to the Institutional Review Board.

**This form must be electronically signed by the Principal Investigator. Your electronic signature certifies that you agree to adhere to the statements above.**





Indiana University Health Ball Memorial Hospital  
Institutional Review Board (IRB)  
**EXPEDITED REVIEW PROCEDURE<sup>1</sup> AND CHECKLIST**

IRBNet ID Number: 754903-1 Date: 5/22/2015  
Principal Investigator: Allyson Garrett  
Study Title: Assessment of Unique Inspiratory Muscle Training Techniques Utilized by Patients with COPD

### Applicability

- A. Research activities that
- (1) present no more than minimal risk to human subjects, and
  - (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- B. The categories in this list apply regardless of the age of subjects, except as noted.
- C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- D. The expedited review procedure may not be used for classified research involving human subjects.
- E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened – utilized by the IRB.
- F. Categories one (1) through seven (7) pertain to both initial and continuing review.

**If you believe your research fits into one or more of the following categories which can be considered for Expedited Review, indicate by checking the appropriate box.** (To check a box, position your I-beam/cursor over the desired box; then double click until "Check Box Form Field Options" appears. Change the default value to "Checked.")

### Categories of Expedited Review

- ☐ 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
- a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: research on marketed drugs that significantly increases the risk or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

<sup>1</sup>An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.



Expedited Procedure and Checklist (continued)

- ☐ 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - b. from other adults and children<sup>2</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- ☐ 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
  - a. hair and nail clippings in a nondisfiguring manner;
  - b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - c. permanent teeth if routine patient care indicates a need for extraction;
  - d. excreta and external secretions (including sweat);
  - e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
  - f. placenta removed at delivery;
  - g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
  - h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
  - i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
  - j. sputum collected after saline mist nebulization.
- ☒ 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
  - a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
  - b. weighing or testing sensory acuity;
  - c. magnetic resonance imaging;
  - d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
  - e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- ☐ 5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
- ☐ 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
- ☒ 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

<sup>2</sup>Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Expedited Procedure and Checklist (continued)

- ☐ 8. Continuing review of research previously approved by the convened IRB as follows:
- a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  - b. where no subjects have been enrolled and no additional risks have been identified; or
  - c. where the remaining research activities are limited to data analysis.
- ☐ 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involved no greater than minimal risk and no additional risks have been identified.

This form must be electronically signed within IRBNet by the Principal Investigator. Your electronic signature indicates you agree that the category(s) checked above do strictly apply to the proposed research study.





Ball Memorial Hospital

BALL STATE  
UNIVERSITY.

**NEEDED!!**

**COPD Patients as Participants in a Research Study!**

Allyson Garrett, a Ball State University undergraduate student, is seeking individuals to participate in a study examining the effectiveness of harmonica playing as a form of inspiratory muscle training.

**WHO?**

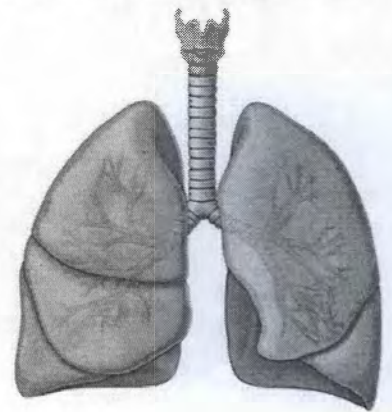
- Individuals with COPD between the ages of 18 and 90

**WHY?**

- We know that exercise conditions our muscles and promotes better and more efficient functioning in our daily lives, so by exercising the muscles of ventilation, it's believed that patients will achieve better and easier breathing. Harmonica training has been shown to be an effective way of doing this, and we are going to conduct a short study to see if we can support that claim.

**WHAT DOES YOUR COMMITMENT TO PARTICIPATING ENTAIL?**

- Filling out a couple of questionnaires prior to and following the study
- Continuing your normal exercise routine with pulmonary rehab 3 times a week
- Harmonica playing 3 times a day for ten minutes each on 3 non-rehab days
- Six weeks of training and data collection accompanied by journal entries



**WHERE?**

- Everything will take place at IU Ball Memorial Hospital's Pulmonary Rehabilitation Program.

**ARE THERE BENEFITS?**

- Participants could potentially gain an understanding of the benefits of inspiratory muscle training on their functional capacity and daily activities, as well as the possible implications of such training on their COPD.
- However, there may be no personal benefit from your participation, but the knowledge received may be of value to humanity.

Simply return this flyer to Heather Cochran in Pulmonary Rehab and you will officially be a part of a pool from which 10-20 participants will be chosen. Additional information will be provided.

If you have any questions, feel free to contact Allyson by email at [apgarrett@bsu.edu](mailto:apgarrett@bsu.edu) or by phone at (765) 465-3376 or Heather Cochran at (765) 747-3773.



Phase II



Ball Memorial Hospital



**NEEDED!!**

**COPD Patients as Participants in a Research Study!**

Allyson Garrett, a Ball State University undergraduate student, is seeking individuals to participate in a study examining the effectiveness of harmonica playing as a form of inspiratory muscle training.

**WHO?**

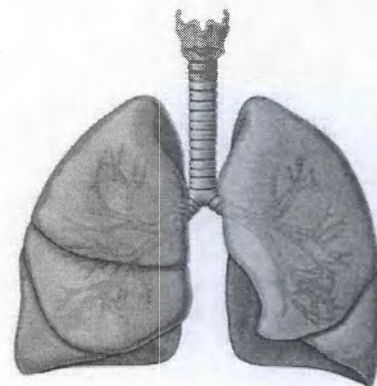
- Individuals with COPD between the ages of 18 and 90

**WHY?**

- We know that exercise conditions our muscles and promotes better and more efficient functioning in our daily lives, so by exercising the muscles of ventilation, it's believed that individuals with COPD will achieve better and easier breathing. Harmonica training has been shown to be an effective way of doing this, and we are going to conduct a short study to see if we can support that claim.

**WHAT DOES YOUR COMMITMENT TO PARTICIPATING ENTAIL?**

- Filling out a couple of questionnaires prior to and following the study
- Exercise three days a week
- Use of a Voldyne, an incentive spirometer, 3 times a day for ten inhalations each time, on 3 non-rehab days
- Six weeks of training and data collection accompanied by journal entries



**WHERE?**

- Everything will take place at IU Ball Memorial Hospital's Pulmonary Rehabilitation Program and at your home, or wherever you choose to complete your exercise training.

**ARE THERE BENEFITS?**

- Participants could potentially gain an understanding of the benefits of inspiratory muscle training on their functional capacity and daily activities, as well as the possible implications of such training on their COPD.
- However, there may be no personal benefit from your participation, but the knowledge received may be of value to humanity.

Simply return this flyer to Heather Cochran in Pulmonary Rehab and you will officially be a part of a pool from which participants will be chosen. Additional information will be provided.

If you have any questions, feel free to contact Allyson by email at [apgarrett@bsu.edu](mailto:apgarrett@bsu.edu) or by phone at (765) 465-3376 or Heather Cochran at (765) 747-3773.





## **APPENDIX B: Informed Consents**



*Consent to Participate in a Minimal Risk Research Study*

**TITLE: ASSESSMENT OF UNIQUE INSPIRATORY MUSCLE TRAINING TECHNIQUES UTILIZED BY PATIENTS WITH COPD**

**What is the purpose of this study & why am I being invited to take part?**

The purpose of this study is to analyze the implications of harmonica playing and Voldyne use on inspiratory muscle strength and subsequent effects on shortness of breath and perception of the difficulty of breathing, activities of daily living (ADLs), and quality of life (QoL). The objective is to assess if one form of training the inspiratory muscles, or the muscles that assist you in breathing, is superior to the other and whether or not harmonica playing is a viable and beneficial component of a pulmonary rehabilitation program. You are being invited to take part in this research study because you are currently a Phase III Pulmonary Rehabilitation patient at IU Health Ball Memorial Hospital with COPD, and are between the ages of 18 and 90. If you volunteer to take part in this study, you will be one of about 10-20 people to do so.

**Who is doing the study?**

The person in charge of this study is Allyson Garrett, a senior Exercise Science major at Ball State University. She is being guided in her research by Nicole Koontz and Heather Cochran. There may be other people on the research team assisting at different times during the study.

**Where is the study going to take place & how long will it last?**

The research procedures will be conducted at IU Health Ball Memorial Hospital. You will need to come to the Cardiopulmonary Rehabilitation facility on your 3 usual rehab days for 6 weeks in order to complete your exercise, in addition to 2 other times, once to complete an orientation and the required questionnaires for the study, and once for a follow-up where you will fill out the same questionnaires in order for us to gauge any progress that was made. The exercise sessions will each require 40 minutes of your time, plus an additional 15 for vital signs such as heart rate and blood pressure. The pre- and post-study information sessions should take 30-60 minutes. The total amount of time you will be asked to volunteer for this study is 18-20 hours over the next 8 weeks.

**What will I be asked to do?**

You will be asked to continue completing your normal exercise routine of 3, 40-minute sessions of exercise each week on your for a time span of 6 weeks, in addition to the use of your harmonica three times a day on three non-rehab days each week over that same 6-week time frame. Each bout of harmonica training should last ten minutes, for a total of thirty minutes each day. At the beginning of the study, you will be asked to fill out an mMRC, a questionnaire that assesses your level of breathlessness along a numerical scale. Also at this time, you will fill out a CAT document, which stands for COPD Assessment Test, which is used to measure the impact that COPD is having on your wellbeing and daily life. These documents will be issued following the 6-week training program as a way to subjectively compare how your respective inspiratory training type has influenced your health. A log sheet will also be provided to you so that you are able to document and keep track of the dates and times in which you are completing your harmonica playing. There are no specific times throughout the day in which you must complete your three bouts of harmonica training, as long as you complete all three bouts throughout the day on those non-rehab days. This will help you keep everything in order, as well as hold you accountable for your participation, but will also help the research team in their collection of data.

**What are the possible risk and discomforts?**

There is minimal risk to participating in this project. However, there is a risk that your identity as a research participant or information you provide could become known. Every effort will be made to protect your privacy and the confidentiality of the information you provide.

**Will I benefit from taking part in the study?**

There may be no personal benefit from your participation, but the knowledge received may be of value to humanity.



**Do I have to take part in the study?**

If you decide to take part in the study, it should be because you really want to volunteer. If you decide not to take part in this study, your decision will have no effect on the care you receive. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you do not want to be in the study, there are no other choices ~~except not to take part in the study.~~

**Who will see the information that I give?**

We will keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what the information is. For example, your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, someone from IU Health Ball Memorial Hospital or the hospital's Institutional Review Board, or another regulatory agency may look at or copy pertinent portions of records that identify you.

**Can my partaking in the study end early?**

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study. The individuals conducting the study, at their discretion, may need to withdraw you from the study.

**Will I receive any rewards for taking part in this study?**

You will not receive any monetary compensation for your participating in this study.

**What if I have questions?**

Before you decide whether to accept the invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have any questions about the study, you can contact the investigator, Allyson Garrett at [apgarrett@bsu.edu](mailto:apgarrett@bsu.edu) or by phone at 765-465-3376. If you have any questions about your rights as a volunteer in this research, contact the IRB Administrator at IU Health Ball Memorial Hospital at 765-747-8458. We will give you a copy of this consent form to take with you.

If you have any questions or concerns about your privacy rights, you should contact the IU Health Ball Memorial Hospital, Inc. Privacy Officer at 765-747-4457.

**What else do I need to know?**

The Ball State University School of Physical Education, Sport, and Exercise Science is providing the necessary funding and material for this study. Neither IU Health Ball Memorial Hospital nor Allyson Garrett will receive financial benefit from this study.

**AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

By signing this form, you are giving permission to Indiana University Health Ball Memorial Hospital to disclose your protected health information (PHI) to the research team for the specific purpose of this research study. PHI is medical information that identifies you, such as: name, address, phone number, medical record number, diagnosis and other details about you.

**What information may be used for research purposes?**

The information that may be used or disclosed for research purposes will help to determine your eligibility for this study. This may include, but is not limited to, the following types of medical information:

- Hospital records and reports
- Admission histories and physicals
- Laboratory and operative reports
- X-ray films and reports
- Treatment and test results
- Other diagnostic and medical procedures
- Information provided by you directly to the Research Team Immunizations
- Allergy reports
- Prescriptions
- Consultations
- Clinic notes
- Any other medical or dental records needed by the Research Team

**Who may receive or use my protected health information?**

- The Research Team
- IU Health Ball Memorial Hospital's Institutional Review Board and their designee
- IU Health Ball Memorial Hospital representatives
- Government representatives, when required by law

Efforts will be made to ensure that your PHI will not be shared with other people outside the research study. However, your PHI may be disclosed to others as required by law and / or to individuals or organizations that oversee the conduct of the study. These individuals and organizations may not be held to the same legal privacy standards as are doctors and hospitals.

**How long will this permission last?**

Your permission will expire or end with the completion of the study. However, you may withdraw or cancel your permission to use and disclose your health information at any time. You do this by sending **written notice** to the Study Team. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new information will be gathered after that date. Information that has already been gathered may still be used and given to others.

**CONSENT**

I have read the above information about the study, **Assessment of Unique Inspiratory Muscle Training Techniques Utilized by Patients with COPD**, and have been given an opportunity to ask questions. I agree to participate in this study and I have been given a copy of this consent document for my own records.

\_\_\_\_\_  
Signature of Study Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Study Participant, in full

\_\_\_\_\_  
Participant's Address

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Obtaining Consent





*Consent to Participate in a Minimal Risk Research Study*

**TITLE: ASSESSMENT OF UNIQUE INSPIRATORY MUSCLE TRAINING TECHNIQUES UTILIZED BY PATIENTS WITH COPD**

**What is the purpose of this study & why am I being invited to take part?**

The purpose of this study is to analyze the implications of harmonica playing and Voldyne use on inspiratory muscle strength and subsequent effects on shortness of breath and perception of the difficulty of breathing, activities of daily living (ADLs), and quality of life (QoL). The objective is to assess if one form of training the inspiratory muscles, or the muscles that assist you in breathing, is superior to the other and whether or not harmonica playing is a viable and beneficial component of a Pulmonary Rehabilitation program. You are being invited to take part in this research study because you are currently a Phase III Pulmonary Rehabilitation patient at IU Health Ball Memorial Hospital with COPD, and are between the ages of 18 and 90. If you volunteer to take part in this study, you will be one of about 10-20 people to do so.

**Who is doing the study?**

The person in charge of this study is Allyson Garrett, a senior Exercise Science major at Ball State University. She is being guided in her research by Nicole Koontz and Heather Cochran. There may be other people on the research team assisting at different times during the study.

**Where is the study going to take place & how long will it last?**

The research procedures will be conducted at IU Health Ball Memorial Hospital. Although it is encouraged that you come to the Cardiopulmonary Rehabilitation facility 3 days a week for 6 weeks in order to complete your exercise, it is not mandated that you do your exercise at the facility; you may complete your exercise elsewhere if you so choose. However, you must come to IU Health Ball Memorial Hospital on at least 2 occasions: once to complete an orientation and the required questionnaires for the study, and once for a follow-up where you will fill out the same questionnaires in order for us to gauge any progress that was made. The exercise sessions will each require 40 minutes of your time, plus an additional 15 for vital signs such as heart rate and blood pressure, if you choose to complete your exercise under the supervision of the faculty of IU Health Ball Memorial Hospital's Cardiopulmonary Rehabilitation facility. The pre- and post-study information sessions should take 30-60 minutes. The total amount of time you will be asked to volunteer for this study is 18-20 hours over the next 8 weeks.

**What will I be asked to do?**

You will be encouraged to complete 3 40-minute sessions of light to moderate aerobic exercise each week for a time span of 6 weeks, in addition to the use of a Voldyne, a volumetric exerciser, three times a day for three days a week over that same 6-week time frame. Each time you will take complete 10 inhalations, for a total of 30 inhalations each day. Education on how to properly use a Voldyne will be provided to you at the start of the study. At the beginning of the study, you will be asked to fill out an mMRC, a questionnaire that assesses your level of breathlessness along a numerical scale. Also at this time, you will fill out a CAT document, which stands for COPD Assessment Test, which is used to measure the impact that COPD is having on your wellbeing and daily life. These documents will be issued following the 6-week training program as a way to subjectively compare how your respective inspiratory training type has influenced your health. A log sheet will also be provided to you so that you are able to document and keep track of the dates and times in which you are completing your Voldyne use. This will help you keep everything in order, as well as hold you accountable for your participation, but will also help the research team in their collection of data. Keep in mind that there are no specific times throughout the day in which you must complete these three bouts as long as you are completing all of them.

**What are the possible risk and discomforts?**

There is minimal risk to participating in this project. However, there is a risk that your identity as a research participant or information you provide could become known. Every effort will be made to protect your privacy and the confidentiality of the information you provide.

**Will I benefit from taking part in the study?**

There may be no personal benefit from your participation, but the knowledge received may be of value to humanity.

**Do I have to take part in the study?**

If you decide to take part in the study, it should be because you really want to volunteer. If you decide not to take part in this study, your decision will have no effect on the care you receive. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you do not want to be in the study, there are no other choices except not to take part in the study.

**Who will see the information that I give?**

We will keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what the information is. For example, your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, someone from IU Health Ball Memorial Hospital or the hospital's Institutional Review Board, or another regulatory agency may look at or copy pertinent portions of records that identify you.

**Can my partaking in the study end early?**

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study. The individuals conducting the study, at their discretion, may need to withdraw you from the study.

**Will I receive any rewards for taking part in this study?**

You will not receive any monetary compensation for your participating in this study.

**What if I have questions?**

Before you decide whether to accept the invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have any questions about the study, you can contact the investigator, Allyson Garrett at [apgarrett@bsu.edu](mailto:apgarrett@bsu.edu) or by phone at 765-465-3376. If you have any questions about your rights as a volunteer in this research, contact the IRB Administrator at IU Health Ball Memorial Hospital at 765-747-8458. We will give you a copy of this consent form to take with you.

If you have any questions or concerns about your privacy rights, you should contact the IU Health Ball Memorial Hospital, Inc. Privacy Officer at 765-747-4457.

**What else do I need to know?**

The Ball State University School of Physical Education, Sport, and Exercise Science is providing the necessary funding and material for this study. Neither IU Health Ball Memorial Hospital nor Allyson Garrett will receive financial benefit from this study.

**AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

By signing this form, you are giving permission to Indiana University Health Ball Memorial Hospital to disclose your protected health information (PHI) to the research team for the specific purpose of this research study. PHI is medical information that identifies you, such as: name, address, phone number, medical record number, diagnosis and other details about you.

APPROVED JUN 17 2015



### What information may be used for research purposes?

The information that may be used or disclosed for research purposes will help to determine your eligibility for this study. This may include, but is not limited to, the following types of medical information:

- Hospital records and reports
- Admission histories and physicals
- Laboratory and operative reports
- X-ray films and reports
- Treatment and test results
- Other diagnostic and medical procedures
- Information provided by you directly to the Research Team Immunizations
- Allergy reports
- Prescriptions
- Consultations
- Clinic notes
- Any other medical or dental records needed by the Research Team

### **Who may receive or use my protected health information?**

- The Research Team
- IU Health Ball Memorial Hospital's Institutional Review Board and their designee
- IU Health Ball Memorial Hospital representatives
- Government representatives, when required by law

Efforts will be made to ensure that your PHI will not be shared with other people outside the research study. However, your PHI may be disclosed to others as required by law and / or to individuals or organizations that oversee the conduct of the study. These individuals and organizations may not be held to the same legal privacy standards as are doctors and hospitals.

### How long will this permission last?

Your permission will expire or end with the completion of the study. However, you may withdraw or cancel your permission to use and disclose your health information at any time. You do this by sending **written notice** to the Study Team. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new information will be gathered after that date. Information that has already been gathered may still be used and given to others.

## CONSENT

I have read the above information about the study, **Assessment of Unique Inspiratory Muscle Training Techniques Utilized by Patients with COPD**, and have been given an opportunity to ask questions. I agree to participate in this study and I have been given a copy of this consent document for my own records.

Signature of Study Participant

Date \_\_\_\_\_

Printed Name of Study Participant, in full

Participant's Address

Signature of Person Obtaining Consent

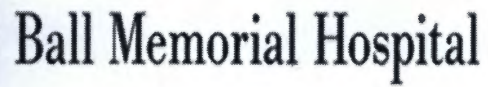
Date \_\_\_\_\_

Printed Name of Person Obtaining Consent

APPROVED JUN 17 2015

## **APPENDIX C: Data Collection Sheets**





B A L L  S T A T E  
U N I V E R S I T Y.

[illegible]





Ball Memorial Hospital



- **If you are currently completing harmonica playing** as a part of your pulmonary rehab program, you will complete three ten-minute sessions on the harmonica on three non-rehab days each week during the 6 week-program.
- **If you are not currently completing harmonica playing** as a part of your pulmonary rehab program, you instead will complete ten inhalations on the Voldyne three times a day on three non-rehab days each week during the 6-week program.
- In order to hold you accountable, we have created a log sheet for you to keep track of when you are doing your three sessions of either the harmonica or Voldyne throughout the day. This will help you and us, as data collectors, as well.
- There are no specific times throughout the day in which you have to complete these three bouts. However, you may find it beneficial to space them out throughout the course of the day when you are feeling your best, such as once in the morning, once in the afternoon, and once in the evening.

**\*\*Please use the example log sheet below as a guide when filling out your dates and times for your harmonica or Voldyne use**

**\*\*Keep in mind, this is just an example; you can complete your three bouts at any time throughout the day as long as you complete all three:**

| <i>Week X</i>    |            |           |
|------------------|------------|-----------|
| Day 1: 5/24/2015 |            |           |
| Time #1          | Time #2    | Time #3   |
| 8:03 a.m.        | 11:55 a.m. | 5:45 p.m. |
| Day 2: 5/27/2015 |            |           |
| Time #1          | Time #2    | Time #3   |
| 8:15 a.m.        | 12:04 p.m. | 6:17 p.m. |
| Day 3: 5/29/2015 |            |           |
| Time #1          | Time #2    | Time #3   |
| 7:55 a.m.        | 11:27 a.m. | 5:32 p.m. |



## Log Sheet for Tracking Harmonica or Voldyne Use By Participants

### *Week 1*

Day 1: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

Day 2: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

Day 3: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

### *Week 2*

Day 1: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

Day 2: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

Day 3: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

### *Week 3*



Day 1: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

Day 2: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

Day 3: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

#### *Week 4*

Day 1: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

Day 2: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

Day 3: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

#### *Week 5*

Day 1: / /

| Time #1 | Time #2 | Time #3 |
|---------|---------|---------|
|         |         |         |

Day 2: / /



| Time #1    | Time #2 | Time #3 |
|------------|---------|---------|
|            |         |         |
| Day 3: / / |         |         |
| Time #1    | Time #2 | Time #3 |
|            |         |         |

| Week 6     |         |         |
|------------|---------|---------|
| Day 1: / / |         |         |
| Time #1    | Time #2 | Time #3 |
|            |         |         |
| Day 2: / / |         |         |
| Time #1    | Time #2 | Time #3 |
|            |         |         |
| Day 3: / / |         |         |
| Time #1    | Time #2 | Time #3 |
|            |         |         |

## **APPENDIX D: COPD Assessment Test (CAT)**





**COPD ASSESSMENT TEST (CAT)**

## How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the Impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

| Example: I am very happy  | ① | <del>②</del> | ③ | ④ | ⑤ | I am very sad  | SCORE                |
|---|---|--------------|---|---|---|--|----------------------|
| I never cough   | ① | ②            | ③ | ④ | ⑤ | I cough all the time   | <input type="text"/> |
| I have no phlegm (mucus) in my chest at all                       | ① | ②            | ③ | ④ | ⑤ | My chest is completely full of phlegm (mucus)                          | <input type="text"/> |
| My chest does not feel tight at all                               | ① | ②            | ③ | ④ | ⑤ | My chest feels very tight  | <input type="text"/> |
| When I walk up a hill or one flight of stairs I am not breathless | ① | ②            | ③ | ④ | ⑤ | When I walk up a hill or one flight of stairs I am very breathless     | <input type="text"/> |
| I am not limited doing any activities at home                     | ① | ②            | ③ | ④ | ⑤ | I am very limited doing activities at home                             | <input type="text"/> |
| I am confident leaving my home despite my lung condition          | ① | ②            | ③ | ④ | ⑤ | I am not at all confident leaving my home because of my lung condition | <input type="text"/> |
| I sleep soundly   | ① | ②            | ③ | ④ | ⑤ | I don't sleep soundly because of my lung condition                     | <input type="text"/> |
| I have lots of energy   | ① | ②            | ③ | ④ | ⑤ | I have no energy at all  | <input type="text"/> |
| <b>TOTAL SCORE</b>  |   |              |   |   |   |  | <input type="text"/> |

Patient Signature: \_\_\_\_\_

Date/Time: \_\_\_\_\_



**COPD ASSESSMENT  
TEST (CAT)**

MEDICAL  
RECORD ORIGINAL

PR INITIAL  
ASSESSMENT

**B-40**

## **APPENDIX E: mMRC Breathlessness Scale**



## mMRC Breathlessness Scale

| Grade | Description of Breathlessness  |
|-------|--|
| 0     | I only get breathless with strenuous exercise  |
| 1     | I get short of breath when hurrying on level ground or walking up a slight hill  |
| 2     | On level ground, I walk slower than people of the same age because of breathlessness, or have to stop for breath when walking at my own pace |
| 3     | I stop for breath after walking about 100 yards or after a few minutes on level ground   |
| 4     | I am too breathless to leave the house or I am breathless when dressing  |

© The Author 2008. Published by Oxford University Press on behalf of the Society of Occupational Medicine. All rights reserved. For Permissions, please email: [journals.permissions@oxfordjournals.org](mailto:journals.permissions@oxfordjournals.org)

### Smoking Cessation

Counseling at every visit

Nicotine Replacement:

Nicotine gum-OTC, Nicotine patch-Rx and OTC, Nicotine lozenge-OTC,  
Nicotine nasal spray-Rx, Nicotine inhaler-Rx

Antidepressant-Bupropion Sr

Varenicline

Endorsed by: COPD Foundation, Jo-Ann LeBuhn Center for Chest Disease, NewYork-Presbyterian Hospital.

This COPD Pocket Consultant is provided by the member institutions of the NewYork-Presbyterian Healthcare System as an educational resource only and should not be considered as offering medical advice. This information should not be used as a substitute for the exercise or receipt of a physician's independent professional judgement in providing advice, diagnosis or treatment for any medical or health condition.

Updated January 2012

**NewYork-Presbyterian  
Healthcare System**

**COPD**  
FOUNDATION

[www.nypsystem.org](http://www.nypsystem.org)  
[www.copdfoundation.org](http://www.copdfoundation.org)